



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-up Exclusive Evaluation Option License: Methods of Treating Giardiasis Using Available Compounds

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a start-up exclusive evaluation option license to practice the inventions embodied in US provisional Applications 61/392,096 (E-211-2010/0-US-01) filed October 12, 2010 and 61/411,509 filed November 9, 2010 (E-211-2010/1-US-01); PCT application No. PCT/US2011/055902 filed October 12, 2011 (E-211-2010/2-PCT-01); US patent application No. 13/878,832 filed April 11, 2013 (E-211-2010/2-US-06); European patent application No. 11773158.8 filed May 2, 2013 (E-211-2010/2-EP-04); Canadian application No. 2,814,694 filed April 11, 2013 (E-211-2010/2-CA-03); Australia application No. 2011316657 filed April 12, 2013 (E-211-2010/2-AU-02); and Indian application No. 1137/KOLNP/2013 filed April 22, 2013 (E-211-2010/2-IN-05); each entitled “Methods of Treating Giardiasis” by Wei Zheng et al. to BrioMed, Inc.,

having a place of business at 1743 S. Westgate Ave, Los Angeles, CA 90025 USA. The patent rights in this invention have been assigned to the United States of America and the University of Maryland.

DATE: Only written comments and/or application for a license that are received by the NIH Office of Technology Transfer on or before [Insert date 15 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Tedd Fenn, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Email: Tedd.Fenn@mail.nih.gov; Telephone: 301-435-5031; Facsimile: 301-402-0220.

SUPPLEMENTARY INFORMATION:

The prospective start-up exclusive evaluation option license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective start-up exclusive evaluation option license may be granted unless, within fifteen (15) days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

This technology includes a group of at least twenty-nine, diverse, commercially available compounds that are newly identified for activity against *Giardia lamblia*

parasites. At least six of the candidate compounds, Bortezomib, Decitabine, Hydroxocobalamin, Amlexanox, Idarubicin, and Auranofin have preexisting FDA approval for human use for other (non-Giardia) conditions. Another three compounds, Fumagillin, Nitarsonsone and Carbadox have preexisting approval for veterinary use for non-Giardia conditions. Additional active compounds identified include: Acivicin, Riboflavin butyrate, BTO-1, GW9662, Dinitrophenol, Deserpidine, Tetramethylthiuram disulfide, Disulfiram, Mitoxantrone, Ecteinascidin 743, 17-allyaminogeldanamycin, Carboquone and Nocodazole. The anti-Giardial activity of these compounds presents a cost saving opportunity for the rapid development of new, better tolerated treatments for the most prevalent human intestinal parasite infection in the United States and the world.

The proposed field of exclusivity may be limited to therapeutics for treatment of Giardia infection in mammals.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: July 9, 2013.

Richard U. Rodriguez, M.B.A.
Director
Division of Technology Development and Transfer
Office of Technology Transfer

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